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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,440	02/05/2004	Michal Daniely	26003	3178

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EXAMINER	
DUFFY, BRADLEY	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
06/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,440	DANIELY ET AL.	
	Examiner	Art Unit	
	BRADLEY DUFFY	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72,73 and 82-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72,73 and 82-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 August 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/9/09, 4/17/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 9, 2009, has been entered.

2. The amendment filed April 9, 2009, is acknowledged and has been entered. Claims 72 and 73 have been amended. Claims 37, 39-40, 54-55 and 57 have been canceled. Claims 82-86 have been newly added.

3. Claims 72-73 and 82-86 are pending in the application and are under examination.

Information Disclosure Statement

4. The references cited in the information disclosure statements filed on April 9, 2009, and April 17, 2009, have been considered. Notably, while the International and European search reports were considered, their citations were crossed out because they fail to comply with 37 CFR § 1.98 (b)(5) (see also MPEP 609).

Grounds of Objection and Rejection Withdrawn

5. Applicant's amendments filed April 9, 2009, have obviated or rendered moot the grounds of rejection set forth in the previous Office action mailed December 11, 2008.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 72-73 and 82-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) In this case, the claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of *identifying* "a single cell having *a morphological abnormality associated with transitional cell carcinoma*", and *identifying* "*a chromosomal abnormality associated with said transitional cell carcinoma* in the same said single cell identified as having said *morphological abnormality associated with transitional cell carcinoma*" in claims 72 and 73. As a first point, these recitations render the claims indefinite because it is unclear how *a morphological abnormality* or *a chromosomal abnormality* is to be identified by these steps. For example, is a *morphological abnormality* identified as a morphological abnormality by the staining of the cells by May-Grunwald-Giemsa, Giemsa, Papanicolau or Hematoxylin-Eosin, or is the *morphological abnormality* identified in some other way? Similarly, is a *chromosomal abnormality* identified as a *chromosomal* abnormality stained by FISH, or is the *morphological abnormality* identified in some other way? Notably, other "morphological" and/or "*chromosomal*" stains are known in the art such as DAPI, and therefore it is submitted that the identifying steps set forth in the instant claims omit essential steps because it is unclear and ambiguous how the abnormalities are identified. Furthermore, since the claims recite a morphological abnormality ***associated*** with transitional cell carcinoma or a chromosomal abnormality ***associated*** with said transitional cell carcinoma, the claims are also indefinite because it is unclear how these abnormalities are necessarily ***associated*** with transitional cell carcinoma. Is the association direct or indirect, are the abnormalities ***associated*** with transitional cell carcinoma because they cause transitional cell carcinoma, are the abnormalities ***associated*** with transitional cell carcinoma because they have been clinically correlated with a diagnosis of transitional cell carcinoma or are the abnormalities associated in some other manner. Without

knowing how the abnormalities are ***associated*** with transitional cell carcinoma the claims cannot be construed unambiguously by one of skill in the art.

Applicant is reminded that in determining whether the claims satisfy the requirement set forth under § 112, second paragraph, M.P.E.P. § 2106 (II) states:

> USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). **Limitations appearing in the specification but not recited in the claim should not be read into the claim**. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" **without importing limitations from the specification into the claims unnecessarily**). *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550- 551 (CCPA 1969). See also *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.") (Emboldened added for emphasis).

M.P.E.P. § 2106 (II) continues:

> While it is appropriate to use the specification to determine what applicant intends a term to mean, a **positive limitation from the specification cannot be read into a claim that does not itself impose that limitation**. A broad interpretation of a claim by USPTO personnel will reduce the possibility that the claim, when issued, will be interpreted more broadly than is justified or intended. An applicant can always amend a claim during prosecution to better reflect the intended scope of the claim.
>
> Finally, when evaluating the scope of a claim, every limitation in the claim must be considered. USPTO personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, **the claim as a whole must be considered**. See, e.g., *Diamond v. Diehr*, 450 U.S. 175, 188-89, 209 USPQ 1, 9 (1981).

Accordingly, rather than requiring that the claims are insolubly ambiguous, the Board of Patent Appeals and Interferences has recently stated in a rare precedential opinion that the "USPTO is justified in using a lower threshold showing of ambiguity to support a finding of indefiniteness under 35 U.S.C. § 112, second paragraph, because the applicant has an opportunity and a duty to amend the claims during prosecution to more clearly and precisely define the metes and bounds of the claimed invention and to more clearly and precisely put the public on notice of the scope of the patent." *Ex parte Miyazaki*, Appeal 2007-3300, November 19, 2008, at p. 12.

In this case, unless it is clear by which steps the abnormalities are to be identified, the scope of the "abnormalities" that are to be identified as set forth in the claims cannot be construed unambiguously.

It is suggested that this issue be remedied by amending the claims to steps that unambiguously identify the "abnormalities" being referred to, which are disclosed in the specification, as filed, because such a limitation would serve to unambiguously identify the "abnormalities" to which the claims are directed.

For these reasons, given the evident ambiguity with which the subject matter of the claims may be interpreted, it is submitted that the claims fail to delineate the metes and bounds of the subject matter regarded as the invention with the clarity and particularity necessary to satisfy the requirement set forth under 35 U.S.C. § 112, second paragraph, so as to permit the skilled artisan to know or determine infringing subject matter.

(b) The claims are also indefinite because claim 72 is directed to a method for identifying transitional cell carcinoma cells and claim 73 is directed to a method for identifying bladder cancer in a subject; yet the claims merely recite processes which indicate that said same single cell is a ***cancerous cell*** (see claims 72 and 73). Notably, the claims do not set forth that the presence of a "morphological" and "*chromosomal*" abnormality in the same cell indicates that the cell is a transitional cell carcinoma cell or that the presence of a "morphological" and "*chromosomal*" abnormality in the same cell indicates bladder cancer in the subject. Accordingly, there is no process step that clearly relates back to the purpose or objective of the claimed invention; consequently, the skilled artisan could not determine whether each and every process step considered essential to the practice of the claimed invention has been included in the body of the claim. Thus, in the absence of a correlative step positively relating the whole of the process to its intended use, as recited in the preamble, the claim fails to delineate the subject matter that Applicant regards as the invention with the requisite degree of clarity and particularity to permit the skilled artisan to know or determine infringing and non-

infringing subject matter and thereby satisfy the requirement set forth under 35 U.S.C. § 112, second paragraph.

(c) Claim 82 is indefinite in the recitation of "wherein the transitional cell carcinoma cells are *associated* with bladder cancer or kidney cancer" How are the transitional cell carcinoma cells *associated* with bladder cancer or kidney cancer? Are the transitional cell carcinoma cells from a bladder cancer or a kidney cancer, are transitional cell carcinoma cells characteristic of a bladder cancer or a kidney cancer or are the transitional cell carcinoma cells associated with bladder cancer or a kidney cancer in some other manner? Without knowing the association between the transitional cell carcinoma cells and bladder cancer or kidney cancer the claim cannot be construed unambiguously. Thus, this claim fails to delineate the subject matter that Applicant regards as the invention with the requisite degree of clarity and particularity to permit the skilled artisan to know or determine infringing and non-infringing subject matter and thereby satisfy the requirement set forth under 35 U.S.C. § 112, second paragraph.

Accordingly, these claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 72, 73, 82, 83 and 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al (Urol Res. 28:57-61, 2000).

As amended, the claims herein recite methods comprising:

(a) staining nucleated cells of a urine sample using a stain selected from the group consisting of May-Grunwald-Giemsa, Giemsa, Papanicolau and Hematoxylin-Eosin to thereby obtain stained nucleated cells;

(b) imaging said stained nucleated cells resultant of steps (a) so as to obtain images of said stained nucleated cells, and;

(c) identifying in said images of step (b) a single cell having a morphological abnormality associated with transitional cell carcinoma

(d) staining said stained nucleated cells resultant of step (a) using fluorescent in situ hybridization (FISH) to thereby obtain stained nucleated cells stained with FISH, and; subsequently;

(e) imaging said nucleated cells stained with FISH resultant of step (d) so as to obtain images of said nucleated cells stained with FISH; and subsequently;

(f) identifying in said images of step (e) a chromosomal abnormality associated with said transitional cell carcinoma in the same said single cell identified in step (c) having said morphological abnormality associated with transitional cell carcinoma; (see claim 72)

or methods comprising:

(a) obtaining a urine sample from the subject;

(b) staining nucleated cells of said urine sample using a stain selected from the group consisting of May-Grunwald-Giemsa, Giemsa, Papanicolau and Hematoxylin-Eosin to thereby obtain stained nucleated cells;

(c) imaging said stained nucleated cells resultant of steps (b) so as to obtain images of said stained nucleated cells, and;

(d) identifying in said images of step (c) a single cell having a morphological abnormality associated with transitional cell carcinoma

(e) staining said stained nucleated cells resultant of step (b) using fluorescent in situ hybridization (FISH) to thereby obtain stained nucleated cells stained with FISH, and; subsequently;

(f) imaging said nucleated cells stained with FISH resultant of step (d) so as to obtain images of said nucleated cells stained with FISH; and subsequently;

(g) identifying in said images of step (f) a chromosomal abnormality associated with said transitional cell carcinoma in the same said single cell identified in step (d) having said morphological abnormality associated with transitional cell carcinoma; (see claim 73). Claims 83 and 85 are further drawn to obtaining the urine samples by catheterization.

Inoue et al teach methods of identifying transitional cell carcinoma cells or diagnosing bladder cancer from a urine sample obtained via catheterization by a bladder washing of a subject, comprising

(a) staining nucleated cells of the sample with Giemsa, Papanicolau to obtain stained nucleated cells;

(b) imaging said stained nucleated cells resultant of steps (a) so as to obtain images of said stained nucleated cells, and;

(c) identifying in said images of step (b) a single cell having a morphological abnormality stained by Giemsa of a transitional cell carcinoma, wherein the transitional cells were marked on the slide

(d) staining said stained nucleated cells resultant of step (a) using fluorescent in situ hybridization (FISH) to thereby obtain stained nucleated cells stained with FISH, and; subsequently;

(e) imaging said nucleated cells stained with FISH resultant of step (d) so as to obtain images of said nucleated cells stained with FISH; and subsequently;

(f) identifying in said images of step (e) chromosome 9 monosomy, i.e., a chromosomal abnormality of a transitional cell carcinoma in the same said single cell identified in step (c) having said morphological abnormality stained by Giemsa (see entire document, e.g., abstract, page 57, right column page 58 and 59; see also Fig. 2a which shows imaging of Giemsa stained single cells identified as having morphological abnormalities of transitional cells stained by Giemsa stain and Fig. 2b which identifies the same single cells as having chromosome 9 monosomy stained by FISH).

Accordingly, because Inoue et al teach methods of staining, imaging and identifying the same single cells from a urine sample as being transitional cells by Giemsa morphological staining and as having chromosome 9 monosomy, i.e., a

morphological abnormality of transitional cell carcinomas, the processes of Inoue et al are deemed to be materially and manipulatively indistinguishable from the claimed process. Therefore, absent a showing of any difference, the processes disclosed by the prior art are deemed to anticipate the claimed processes.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 72, 73, 84 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al (Urol Res. 28:57-61, 2000), in view of US Patent 6,418,236 (Ellis et al, July 9, 2002, of record).

Claims 72 and 73 are described supra. Claims 84 and 86 are further drawn herein to said imaging being effected using an automated cell imaging device capable of at least dual imaging.

Inoue et al teach that which is set forth in the above rejection of claims 72 and 73 under 35 U.S.C. 102(b).

While Inoue et al teach methods of staining, imaging and identifying the same single cells from a urine sample as being transitional cells by Giemsa morphological staining and as having chromosome 9 monosomy, i.e., a morphological abnormality of transitional cell carcinomas that are materially and manipulatively indistinguishable from the claimed processes set forth in claims 72 and 73, Inoue et al does not expressly teach imaging the cells with an automated imaging device capable of dual imaging.

This deficiency is made up for in the teachings of US Patent 6,418,236. US Patent 6,418,236 teaches automated image analysis using a microscope capable of dual imaging to image cells stained with two stains, wherein the stains can be Giemsa stain, in situ hybridization stains and that the stains can be fluorescent stains (see entire document, e.g., column 1, lines 26-59, column 4, lines 31-67, column 5, lines 1-15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to identify transitional cell carcinoma cells from a urine sample, by staining nucleated cells of a urine sample by the processes of Inoue et al, and imaging the stained cells with the automated microscope capable of dual imaging as taught by US Patent 6,418,236 to identify the same single cells as transitional cell carcinoma cells.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention was made to identify transitional cell carcinoma cells by such processes because the stains of Inoue et al were known in the art to identify transitional cell carcinoma cells while the automated

imaging microscope of US Patent 6,418,236 would allow for faster processing of samples. For example, US Patent 6,418,236 teaches that automated imaging analysis "eliminates the need for operator input to locate biological objects or areas of interest for analysis" (see column 8, lines 30-32). Furthermore, the microscope of US Patent 6,418,236 could image the cells stained by the processes of Inoue et al because it can image Giemsa stain and fluorescent stains. Thus, there would be an advantage and a reasonable expectation of success in identifying transitional cell carcinoma cells from a urine sample, by staining nucleated cells of a urine sample with the stains of Inoue et al and imaging the stained cells with the automated microscope capable of dual imaging as taught by US Patent 6,418,236 to identify the same single cells as transitional cell carcinoma cells, in view of the references.

For these reasons, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

13. Claims 72, 73, 84 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al (Urol Res. 28:57-61, 2000), in view of Kaplinsky (43rd ASH Annual Meeting, Blood, 98(Part 2):348b, 2001, IDS filed 4/9/08).

Claims 72 and 73 are described supra. Claims 84 and 86 are further drawn herein to said imaging being effected using an automated cell imaging device capable of at least dual imaging.

Inoue et al teach that which is set forth in the above rejection of claims 72 and 73 under 35 U.S.C. 102(b).

While Inoue et al teach methods of staining, imaging and identifying the same single cells from a urine sample as being transitional cells by Giemsa morphological staining and as having chromosome 9 monosomy, i.e., a morphological abnormality of transitional cell carcinomas that are materially and manipulatively indistinguishable from the claimed processes set forth in claims 72 and 73, Inoue et al does not expressly teach imaging the cells with an automated imaging device capable of dual imaging.

This deficiency is made up for in the teachings of Kaplinsky. Kaplinsky teaches automated image analysis using a microscope capable of dual imaging to image the same cells stained with Giemsa stain and fluorescent in situ hybridization (FISH) stains (see entire document, e.g., abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to identify transitional cell carcinoma cells from a urine sample, by staining nucleated cells of a urine sample by the processes of Inoue et al, and imaging the stained cells with the automated microscope capable of dual imaging as taught by Kaplinsky to identify the same single cells as transitional cell carcinoma cells.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention was made to identify transitional cell carcinoma cells by such processes because the stains of Inoue et al were known in the art to identify transitional cell carcinoma cells while the automated imaging microscope of Kaplinsky would allow for faster processing of samples. For example, Kaplinsky teaches that automated imaging analysis "provides two important features: scanning large number of cells, and performing combined analysis of morphology and FISH on the same cells" (see abstract, lines 6-8). Thus, there would be an advantage and a reasonable expectation of success in identifying transitional cell carcinoma cells from a urine sample, by staining nucleated cells of a urine sample with the stains of Inoue et al and imaging the stained cells with the automated microscope capable of dual imaging as taught by Kaplinsky to identify the same single cells as transitional cell carcinoma cells, in view of the references.

For these reasons, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

14. No claim is allowed.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Halling et al (of record) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in cells stained with FISH stains. Bubendorf et al (of record) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in cells stained with standard Papanicolaou stain or FISH stains. Darzynkiewicz et al (of record) discloses an automated cell-imaging device capable of dual imaging. Shimoni et al (of record) discloses an automated cell-imaging device capable of dual imaging of cells stained with a May-Grunwald-Giemsa stain and FISH probes. Boon et al (of record) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in cells stained with a Giemsa stain or a Papanicolaou stain. Otto et al (of record) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in cells stained with a Hematoxylin stain and an Eosin stain. US Patents 6,174,681 (2001), 6,376,188 (2002) and 7,232,655 (2007) (all Halling et al) disclose a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in the same single cells stained with a morphological stain, such as DAPI and FISH stains. Placer et al (Eur. Uro. 42:547-552, 2002) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in cells stained with standard Papanicolaou stain or FISH stains. Dalquen et al (Can. Cyto. 96:374-379, 2002) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in cells stained with standard Papanicolaou stain or FISH stains. Sokolova et al (J. Mol. Diag., 2(3):116-123, 2000) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in the same single cells stained with DAPI and FISH stains. Mezzelani et al (Cyto. 13:317-325, 2002) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in the same single cells stained with DAPI and FISH stains.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30 PM, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
June 3, 2008